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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,938	09/02/2003	Manfred Watzele	RDID03056US	2575
23690	7590	05/31/2006		
Roche Diagnostics Corporation, Inc. 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457			EXAMINER MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/652,938	WATZELE ET AL.	
	Examiner	Art Unit	
	Krishnan S. Menon	1723	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-17 are pending as amended 5/19/06.

#### ***Claim Rejections - 35 USC § 112***

**A.** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1 and 17 recite "... a separate and distinct semipermeable membrane ...", which does not seem to have support in the specification and claims as originally filed. While the figures show separate pieces of membranes attached to the wells, there is no indication of any distinctness between them. (Distinct: distinguishable to the eye or mind as discrete, Webster's Dictionary).

**B.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1723

Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations recited for the fixing part(s) of the membrane in claim 7 is repeated from claim 1; the recitation in claim 1 being narrower than that in claim 7, which is indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/44877 (US equivalent in English: Schels et al, US 6,670,173; herein after, Schels) in view of Manns (US 5,047,215) and/or Wolf et al (US 5,462,874).

Schels teaches a microdialysis device having a sample chamber (12) and dialysate chamber 10 separated by membrane 7; the periphery of the membrane 7 is fixed in compression between the groove on the circumferential ring part of the chamber 10 and the ridge on the bottom face of the sample chamber wall (see figure 5; and also figures 2-4). Sample chamber is open only to dialysate chamber 10 via the membrane 7 – having a individual dialysate chambers for the sample chamber. The membrane is cellulose acetate (column 4 line 63).

The teaching of the reference differs from the instant claims in the plurality of sample chambers, common dialysate chamber, dimensions such as wall thickness, the 3 mm difference in the diameter between the sample chamber and the circumferential sidewall of the sample chamber, the membrane area, spacing of the sample chambers and the number of sample chambers in the device. Manns reference teaches 96-well multiwell structure (figure 1) with common dialysate chamber, cellulosic membrane (column 4 lines 29-35), membrane clamped in groove and rib (see figures), membrane area is about 32 sq.mm. (column 1 lines 15-20) . It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Manns in the teaching of Schels for having a multiwell device for simultaneously handling multiple samples as taught by Manns (column 1 lines 10-20) for bioreactions as taught by Schels. Such multiwell plates are also well known in the art as taught by Manns (column 1 lines 10-20). Wolf also teaches such multiwell plates for dialysis, wherein the multiwell plates are removable from the dialysate chamber (see figures 3 and 5), with single dialysate chamber or separate dialysate chamber for each well, and separate membrane pieces for each well. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Wolf in the teaching of Schels for a multi-well dialysate chamber as taught by Wolf for the advantages taught by Wolf (see abstract and column 4 line 58 – column 5 line 12).

Dimensional differences such as the 3 mm diameter difference, or shape such as the conical bottom of the fixing part are not patentable unless applicant can show with evidence of unobviousness. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220

Art Unit: 1723

USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

### ***Response to Arguments***

Applicant's arguments filed 5/19/06 have been fully considered but they are not persuasive.

The arguments are already addressed in the rejection.

Argument that the Schels reference has the pins (36), and therefore the "3 m" dimension cannot be achieved is not persuasive, because the centering of the membrane in the well can be done without the pins; since the membrane has diameter equal to the internal diameter of the well, it will self-center. Also, figure 3 and 4 of Schels does not teach the pins, showing that the pins are not necessary for the assembly. Moreover, those pins are for helping with the assembly, which is not structurally required for the finished product, since the wells are not disassembled and reassembled during normal use.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1723

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S Menon  
Examiner  
Art Unit 1723



5/27/06